

HOGAN & HARTSON  
L.L.P.

MARTIN J. HAHN  
PARTNER  
(202) 637-5926  
MJHAHN@HHLAW.COM

September 9, 2004

COLUMBIA SQUARE  
555 THIRTEENTH STREET, NW  
WASHINGTON, DC 20004-1109  
TEL (202) 637-5600  
FAX (202) 637-5910

*BY ELECTRONIC AND REGULAR MAIL*

Ms. Kathleen Ellwood  
Division of Nutrition Programs and Labeling  
Office of Nutritional Products, Labeling and  
Dietary Supplements  
CFSAN, U.S. Food and Drug Administration  
Room 4A026, HFS-830  
5100 Paint Branch Parkway  
College Park, MD 20740

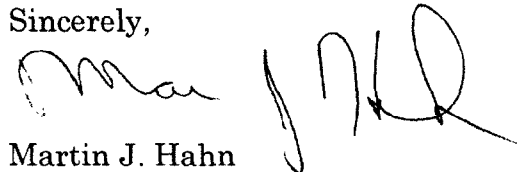
Re: Health Claim Petition: Dietary supplementation of Crystalline  
Glucosamine Sulfate (Glucosamine Sulfate Sodium Chloride-USP/NF  
2003) reduces the risk of osteoarthritis joint deterioration and related  
joint pain and limitation of function.

Dear Ms. Ellwood:

We are writing this letter on behalf of our client, Rotta  
Pharmaceuticals Inc. (Rotta). Rotta agrees to extend the agency review period for  
the above-referenced health claim until October 1, 2004, as requested by Louisa  
Nickerson, Esq., during our telephone conversation this afternoon.

If you have any questions, please contact us.

Sincerely,



Martin J. Hahn

cc: Louisa T. Nickerson, Esq.  
Gloria J. Overholser, Esq.

2004P-0060

LET 9